K003178

DEC 1 4 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Kay A. Taylor

Date prepared: October 10, 2000

Predicate device

The ELECSYS® HCG + Beta Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the AXSYM Total Beta HCG test (K935673) and the Elecsys® HCG Assay (K961487.)

Device Name

Proprietary name: ELECSYS® HCG + Beta Test System

Common name: Beta HCG Test

Classification name: System, Test, Human Chorionic Gonadotropin

Device description

The ELECSYS® HCG + Beta Test System is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

510(k) Summary, continued

Intended use

For the quantitative determination of the sum of human chorionic gonadotropin (hCG) plus the hCG 9 subunit in human serum and plasma.

Indication for use

The Elecsys® HCG + Beta HCG Test System is indicated for the early detection of pregnancy.

Substantial equivalence - similarities

The following table compares the ELECSYS® HCG + Beta Test System, with the predicate device.

Feature	New Device ELECSYS® HCG + Beta Test System	Predicate Device (AxSym Total Beta HCG)	Predicate Device (Elecsys HCG Assay)
Intended use	The quantitative determination of the sum of human chorionic gonadotropin (hCG) plus the hCG 9 subunit	The quantitative and qualitative determination of beta human chorionic gonadotropin	The quantitative determination of human chorionic gonadotropin.
Indication for use	For the early detection of pregnancy	For the early detection of pregnancy	For the early detection of pregnancy
Sample type	Human serum and plasma	Human serum and plasma	Human serum and plasma
Traceability	3'd IRP WHO Reference Standard 75/537	Not included in reagent package insert.	3'd IRP WHO Reference Standard 75/537

510(k) Summary, continued

Substantial equivalence - differences

The following table compares the ELECSYS® HCG + Beta Test System, with the predicate device.

Feature	New Device ELECSYS® HCG + Beta Test System	Predicate Device (AxSym Total Beta HCG)	Predicate Device (Elecsys HCG Assay)
Assay principle	Electrochemilumines cence immunoassay: sandwich principle	Microparticle Enzyme Immunoassay (MEIA) technology	Electrochemiluminesce nce immunoassay: sandwich principle
Instrument	Elecsys® family of immunoassay analyzers	Abbott AxSYM System	Elecsys® family of immunoassay analyzers
Measuring range	0.100-10,000 mIU/mL Upper limit 1,000,000 with sample dilution	2.0 - 1000 mIU/mL Upper limit 200,000 with automatic predilution	0.50 - 10,000 mIU/mL Upper limit 1,000,000 with sample dilution

Substantial equivalence – performance characteristics

The performance characteristics of the ELECSYS® HCG + Beta Test System and the predicate device are compared in the table below.

Feature	New Device ELECSYS® HCG + Beta Test System	Predicate Device (AxSym Total Beta HCG)	Predicate Device (Elecsys HCG Assay)
Within-Run imprecision (%CV)	• 4.5% at 4.26 mIU/mL • 3.3% at 10.8 mIU/mL • 2.8% at 1751 mIU/mL • 3.0% at 7.15 mIU/mL • 2.6% at 24.8 mIU/mL	• 3.76% at 25.41 mIU/mL • 3.56% at 154.50 mIU/mL • 3.18% at 781.43 mIU/mL	• 4.46% at 24.80 mIU/mL • 3.29% at 35.39 mIU/mL • 2.74% at 854.30 mIU/mL
Total imprecision (%CV)	• 5.0% at 4.26 mIU/mL • 3.8% at 10.8 mIU/mL • 3.2% at 1751 mIU/mL • 3.3% at 7.15 mIU/mL • 3.1% at 24.8 mIU/mL	• 5.59% a5 25.41 mIU/mL • 4.43% at 154.50 mIU/mL • 4.11% at 781.43 mIU/mL	• 5.81% at 24.80 mIU/mL • 3.87% at 35.39 mIU/mL • 4.45% at 854.30 mIU/mL
Analytical sensitivity	0.1 mIU/mL	2.0 mIU/mL	.500 mIU/mL
Method comparison	• Comparison to Elecsys HCG STAT (X) Y = -.30 + 0.97 X. • Comparison to Abbott AxSYM (X) Y = 0.39 + 1.05 X	Comparison to Abbott IMX Beta HCG: Y = .96 X +2.2	Comparison to Enzymun-Test HCG: Y = 1.29 X – 4.05

Substantial equivalence – performance characteristics, continued

The performance characteristics of the ELECSYS® HCG + Beta Test System and the predicate device are compared in the table below.

Feature	New Device ELECSYS® HCG + Beta Test System	Predicate Device (AxSym Total Beta HCG)	Predicate Device (Elecsys HCG Assay)
Limitations	• Bilirubin - no significant interference up to 24 mg/dL bilirubin • Hemoglobin - no significant interference up to 1.0 g/dL • Lipemia - no significant interference up to 1400mg/dL Intralipid • Biotin – no significant interference up to 80 ng/mL • Rheumatoid Factor - No significant interference up to 3400 U/mL	• Bilirubin - <5% interference at 20 mg/dL • Hemoglobin - <8% interf3rence at 1000 mg/dL • Triglycerides <10% interference at 1000 mg/dL	• Bilirubin - no significant interference up to 25 mg/dL • Hemoglobin - no significant interference up to 1 g/dL • Lipemia - no significant interference up to 1500 mg/dL Intralipid • Biotin – no significant interference up to 30 ng/mL • Rheumatoid factor- no significant interference up to 667 U/mL

510(k) Summary, continued

Substantial equivalence – performance characteristics, continued

Feature	New Device ELECSYS® HCG + Beta Test System	Predicate Device (AxSym Total Beta HCG)	Predicate Device (Elecsys HCG Assay)
Limitations, continued	• In patients receiving biotin therapy (>5mg/day), sampling should take place at least 8hr after last biotin dose. • No high dose hook effect up to 750,000 mIU/mL • Erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies • Due to a carryover on Elecsys 1010 analyzers of up to % X 10-6 from highly concentrated samples, results obtained for low-concentration samples can be erroneous. Verify all implausible results. • The Elecsys HCG + β findings should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	• Total protein <2% interference at 3.5-10.7 g/dL • Should be used in conjunction with other data • Detection of very low levels of β-hCG does not rule out pregnancy. Patients with very low levels should be resampled and reassayed after 48 hr. • Elevated hCG levels have been associated with some abnormal physiological states and should be considered if consistent with the clinical evidence • Specimens from patients who have received preparations of mouse monoclonal antibodies may show falsely elevated or depressed results • HCG levels may appear consistently elevated due to the presence of heterophilic antibodies or nonspecific protein binding.	• In patients receiving biotin therapy (>5mg/day), sampling should take place at least 8hr after last biotin dose. • No high dose hook effect up to 412,400 mIU/mL • Erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies. • The test should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Roche Diagnostics Corporation
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Indianapolis, Indiana 46250-0457

DEC 1 4 2000

Re: K003178
Trade Name: ELECSYS® HCG + Beta Test System
Regulatory Class: II
Product Code: DHA, JIS
Regulatory Class: I
Product Code: JJY
Dated: October 10, 2000
Received: October 11, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K003178

Device Name: **ELECSYS® HCG + Beta Test System**

Indications For Use: **For the in vitro quantitative determination of the sum of human chorionic gonadotropin (hCG) plus the hCG β subunit in human serum and plasma. The Elecsys® HCG + Beta Test System is intended for use in the early detection of pregnancy.**

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 003178

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)